U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

February 3, 2020

TO: Members, Committee on Energy and Commerce

FROM: Committee Minority Staff

RE: Hearing entitled "Vaping in America – E-Cigarette Manufacturers' Impact on Public Health"

The Subcommittee on Oversight and Investigations will hold a hearing on Wednesday, February 5, 2020, at 10:30 a.m. in 2123 Rayburn House Office Building, entitled "Vaping in America – E-Cigarette Manufacturers' Impact on Public Health."

I. WITNESSES

- K.C. Crosthwaite, Chief Executive Officer, JUUL Labs, Inc.;
- Ricardo Oberlander, President and Chief Executive Officer, Reynolds American Inc.;
- Ryan Nivakoff, Chief Executive Officer, NJOY, LLC;
- Antoine Blonde, President, Fontem US, Inc.; and
- Jerry Loftin, President, Japan Tobacco International USA, Inc.

II. BACKGROUND

a. E-cigarettes

Electronic cigarettes (e-cigarettes) produce an aerosol by heating a liquid that usually contains nicotine, flavorings, and other chemicals that help to make the aerosol users inhale into their lungs.[1] Vaping devices can also be used to deliver marijuana and other drugs. Users inhale this aerosol into their lungs, and bystanders can also breathe in this aerosol when the user exhales into the air. E-cigarettes come in different shapes and sizes and are known by different names such as "e-cigs," "e-hookahs," "mods," "vape pens," "vapes," "tank-systems," and "electronic nicotine delivery systems (ENDS)."[2] Some e-cigarettes look like regular cigarettes, cigars, or pipes, but others can look like pens or USB sticks.[3]

[1] Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, *About Electronic Cigarettes (E-Cigarettes), available at* https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html#what-are-e-cigarettes (last accessed Sept. 23, 2019).
[2] *Id.*
[3] *Id.*

The aerosol from e-cigarettes can contain harmful and potentially harmful substances, including nicotine, and ultrafine particles that can be inhaled deep into the lungs, flavoring such as diacetyl—a chemical linked to a serious lung disease—volatile organic compounds, cancer-causing chemicals, and heavy metals such as nickel, tin, and lead.[4] According to the Centers for Disease Control and Prevention (CDC), it is difficult for consumers to know what e-cigarette products contain. For example, some e-cigarettes labeled as "nicotine free" have been found to contain trace amounts of nicotine.[5] In addition, other countries regulate the amount of nicotine in e-cigarettes, but the United States does not currently have a nicotine limit. As a result, nicotine levels vary by manufacturer and product.

According to the CDC, "[e]-cigarettes have the potential to benefit adult smokers who are not pregnant if used as a complete substitute for regular cigarettes and other smoked tobacco products."[6] While some e-cigarette products can be less harmful than regular cigarettes, e-cigarettes are not harmless. Scientists are still learning about the long-term health effects from using e-cigarettes. What is known is that most e-cigarettes contain nicotine; e-cigarette aerosols can contain substances that harm the body; and e-cigarettes can cause unintended injuries—such as defective e-cigarette batteries causing fires and explosions, or acute nicotine exposure causing poisoning from swallowing, breathing, or absorbing e-cigarette liquid through skin or eyes.[7] For example, nationally, approximately 50 percent of calls to poison control centers for e-cigarettes are for kids five years of age or younger.[8]

E-cigarettes can be closed or open systems. There are two types of closed system e-cigarettes. One has a pre-filled, disposable cartridge that attaches to rechargeable batteries (reusable closed system) and the other is a single-use product that cannot be recharged (disposable closed system). Open system e-cigarettes can be filled with any e-liquid and can have lithium batteries. Most U.S. tobacco companies make closed system products with replaceable cartridges that have reliable, consistent, and accurate ingredient and nicotine labels.[9]

---

[4] U.S. Department of Health and Human Services, Public Health Service, Office of the Surgeon General, *E-cigarette Use Among Youth and Young Adults: A Report of the Surgeon General* (2016), *available at* https://www.cdc.gov/tobacco/data_statistics/sgr/e-cigarettes/pdfs/2016_sgr_entire_report_508.pdf.

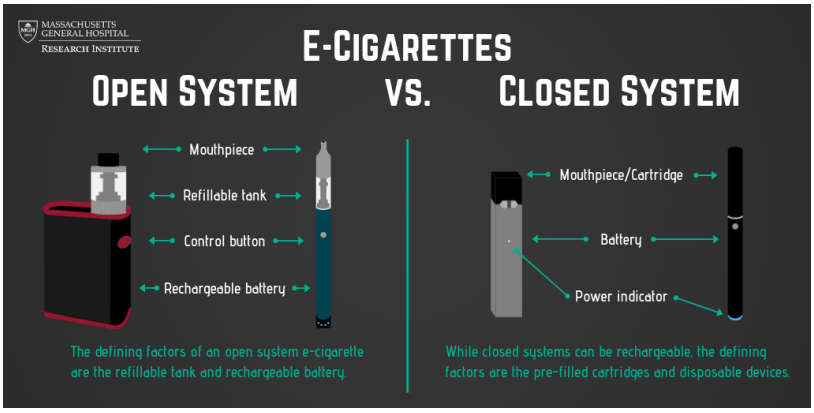
[5] Maciej L. Goniewicz, Ribhav Gupta, et al., Nicotine levels in electronic cigarette refill solutions: a comparative analysis of products from the U.S., Korea, and Poland, Int J Drug Policy (2015 June ; 26(6): 583–588), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4457636/pdf/nihms661813.pdf.

[6] Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, *Electronic Cigarettes What's The Bottom Line*, *available at* https://www.cdc.gov/tobacco/basic_information/e-cigarettes/pdfs/Electronic-Cigarettes-Infographic-p.pdf (last accessed on Sept. 22, 2019).

[7] Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, *About Electronic Cigarettes (E-Cigarettes)*, *available at* https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html#what-are-e-cigarettes (last accessed Sept. 23, 2019).

[8] Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, Smoking & Tobacco Use, Quick Facts on the Risks of E-cigarettes for Kids, Teens, and Young Adults (last updated Jan. 3, 2020), *available at* https://www.cdc.gov/tobacco/basic_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html.

[9] Mass General Research Institute Blog, Pediatric Research, *Not All E-Cigarettes are the Same: What Parents Need to Know* (Oct. 16, 2018), *available at* https://mghresearchinstitute.com/2018/10/16/e-cigarettes-and-adolescents-a-break-down-of-products-and-preferences/.



b. Federal Laws and Regulations

FDA oversees all pathways to market and distribute tobacco products in the U.S. legally. To introduce a new tobacco product to market, including ENDS, manufacturers must follow one of three pathways, otherwise the product may not be legally marketed in the U.S. The manufacturer must file a premarket tobacco product application (PMTA), demonstrate substantial equivalence, or request exemption from demonstrating substantial equivalence.[10]

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) was signed into law on June 22, 2009.[11] The Tobacco Control Act gives the U.S. Food and Drug Administration (FDA) the authority to regulate the manufacturing, distribution, and marketing of tobacco products. Specifically, the Tobacco Control Act restricts tobacco marketing and sales to youth, requires smokeless tobacco product warning labels, places requirements on "modified risk" claims, requires disclosure of ingredients in tobacco products, and preserves state, local, and tribal authority.[12]

Cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco were immediately subject to the provisions of the Tobacco Control Act and FDA's regulatory authority. For other types of tobacco products, section 901(b) of the Food Drug and Cosmetic Act (21 U.S.C. 387a(b)) grants FDA the authority to deem those products subject to the law as well. Products made or derived from tobacco and intended for human consumption—including components and parts of tobacco products, whether or not they are themselves made or derived from tobacco—fall under the definition of tobacco product. Those products include a number of widely used and previously unregulated products, such as cigars, pipe tobacco, waterpipes (or

[10] U.S. Food & Drug Administration, U.S. Department of Health and Human Services, *Market and Distribute a Tobacco Product*, *available at* https://www.fda.gov/tobacco-products/products-guidance-regulations/market-and-distribute-tobacco-product (last accessed Jan. 23, 2020).
[11] Pub. L. 111-31, Family Smoking Prevention and Tobacco Control and Federal Retirement Reform (June 22, 2009), *available at* https://www.govinfo.gov/content/pkg/PLAW-111publ31/pdf/PLAW-111publ31.pdf.
[12] U.S. Food and Drug Administration, U.S. Department of Health and Human Services, *Family Smoking Prevention and Tobacco Control Act – An Overview*, *available at* https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/family-smoking-prevention-and-tobacco-control-act-overview (last accessed Sept. 23, 2019).

hookah), dissolvable products, e-cigarettes and other electronic nicotine delivery systems (ENDS), collectively, the "newly deemed products."[13]

FDA finalized a rule effective August 8, 2016, which extended the agency's regulatory authority to all tobacco products, including electronic smoking devices, subject to the Food, Drug, and Cosmetic Act, including immediate restrictions on the sale and distribution of tobacco products. It immediately became illegal to sell e-cigarettes and other ENDS to anyone under age 18. Retailers became legally responsible for requiring age verification by photo ID for anyone under age 27 to purchase a tobacco product. All deemed products, including ENDS products, became subject to the PMTA requirements in the Tobacco Control Act, which meant that any ENDS product not on the market as of February 15, 2007, is considered a new tobacco product that must be authorized by the FDA to be on the market.[14]

On July 27, 2017, FDA announced a four-year delay of the 2018 PMTA deadline for manufacturers of deemed tobacco products and extended the deadline to 2022. The FDA announced it would seek input from the public on a variety of topics, including approaches to regulating kid-appealing flavors in e-cigarettes and cigars, and intended to issue Advance Notice of Proposed Rulemaking to seek public comment on the role that flavors, including menthol, in tobacco products play in attracting youth, and may play in helping some smokers switch to potentially less harmful forms of nicotine delivery. The FDA also planned to finalize guidance on how it intended to review PMTAs for ENDS.[15]

In March 2018, the American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association Campaign for Tobacco-Free Kids and Truth Initiative filed a lawsuit against the FDA demanding that the FDA reinstate the original deadline and begin enforcing the requirement for premarket review of all deemed products that were on the market as of August 8, 2016.[16]

In July 2019, the U.S. District Court for the Maryland Southern District ruled to set aside FDA's guidance that gave e-cigarette companies until 2022 to file PMTAs to sell their products. The Court ordered that applications must be submitted to FDA no later than May 12, 2020, for products that were on the market as of August 6, 2016. The order provided a one-year period

---

[13] U.S. Food and Drug Administration, U.S. Department of Health and Human Services, *FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales, and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements (Revised)** (Mar. 2019), *available at* https://www.fda.gov/media/97664/download.

[14] Ned Sharpless, MD, Acting Commissioner, U.S. Food and Drug Administration, U.S. Department of Health and Human Services, *How FDA is Regulating E-Cigarettes, available at* https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/how-fda-regulating-e-cigarettes (last accessed Sept. 23, 2019).

[15] U.S. Food and Drug Administration, U.S. Department of Health and Human Services, *FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death* (July 27, 2017), *available at* https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death.

[16] American Academy of Pediatrics, *et al.*, v. Food and Drug Administration, *et al.*, Civil Action No. 8:18-cv-883-PWG (filed Mar. 27, 2018), *available at* https://www.tobaccofreekids.org/assets/content/press_office/2018/2018_03_27_filing.pdf.

during which those products may remain on the market pending FDA review if the applications were filed timely, but also clarified FDA may enforce the premarket review provision prior to May 12, 2020, or during the review period.[17]

On September 20, 2019, the FDA announced a proposed rule to establish requirements related to the basic content and format of PMTAs as part of the agency's continued commitment to its oversight of e-cigarettes and other tobacco products. The proposed rule, when finalized, would also establish the procedure by which FDA would review PMTAs and the requirements for manufacturers to maintain records establishing the legal marketing status of their tobacco products. To date, the FDA has not finalized the rule.

On December 20, 2019, President Trump signed legislation to amend the Food, Drug, and Cosmetic Act, and raise the federal minimum age of sale of tobacco products from 18 to 21.[18] According to FDA, "[i]t is now illegal for a retailer to sell any tobacco product – including cigarettes, cigars and e-cigarettes – to anyone under 21."[19]

FDA's January 2, 2020, enforcement guidance on flavored products is discussed below.

c. Youth E-Cigarette Use

Recent data shows a drastic increase in use of e-cigarettes by youth. According to the National Youth Tobacco Survey, 27.5 percent of youths reported using e-cigarettes in 2019, compared with 20.8 percent in 2018. Just three years ago, the number was at 11.3 percent.[20] The effects of nicotine on humans are not well-studied, although adolescents appear to be particularly vulnerable to it, with some evidence suggesting it can harm brain development. Using nicotine in adolescence can harm the parts of the brain that control attention, learning, mood, and impulse control. Using nicotine in adolescence may also increase risk for a future substance use disorder to other drugs.[21] These trends raise concerns that even if e-cigarettes help some adults to quit more harmful combustible cigarettes, these products may be attracting young people into a nicotine habit. However, while the trend of e-cigarette use has gone up over the past two years, the youth use of cigarettes has continued to decline, as shown by the chart below.

---

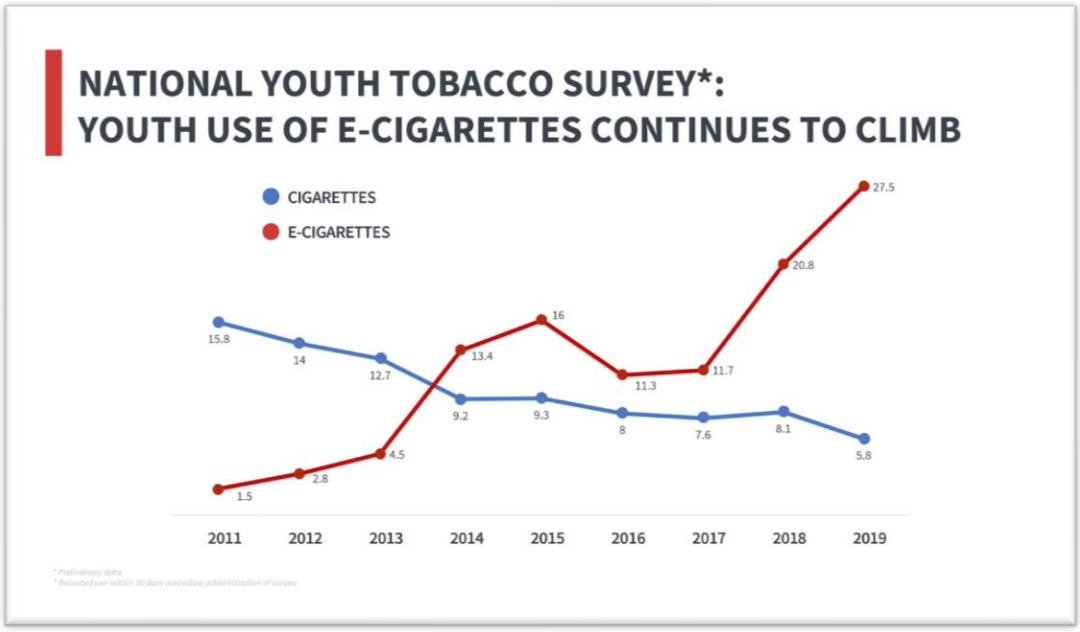
[17] American Academy of Pediatrics, *et al.,* v. Food and Drug Administration, *et al.,* Case 8:18-cv-00883-PWG, (filed July 12, 2019), *available at* https://www.tobaccofreekids.org/assets/content/press_office/2019/2019_07_12_fda_memo.pdf.

[18] U.S. Food and Drug Administration, Selling Tobacco Products in Retail Stores, (Dec. 20, 2019), *available at* https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/selling-tobacco-products-retail-stores.

[19] *Id.*

[20] U.S. Food and Drug Administration, U.S. Department of Health and Human Services, *Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products* (Sept. 11, 2019), *available at* https://www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non.

[21] Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, *Quick Facts on the Risks of E-cigarettes for Kids, Teens, and Young Adults, available at* https://www.cdc.gov/tobacco/basic_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html#one (last accessed Sept. 23, 2019).



The Cleveland Clinic Journal of Medicine reports there are currently no established treatment approaches for adolescents who have become addicted to vaping. Their review of the literature regarding treatment modalities used for treating adolescent use of tobacco and marijuana suggests nicotine replacement therapy and cognitive behavioral therapy may be helpful in treating teen vaping addiction; however, more research is needed to determine the effectiveness of these treatments in youth addicted to vaping.[22]

As part of FDA's Comprehensive Plan for Tobacco and Nicotine Regulation, FDA has a Youth Tobacco Prevention Plan, which contains a series of efforts surrounding access, marketing, and education to stop youth use of tobacco products, especially e-cigarettes.[23] Specifically, FDA is conducting more than one million retail inspections; pursuing no tobacco sales orders to retail locations; taking actions on flavored tobacco products; addressing the epidemic of e-cigarette use; warning retailers for selling e-cigarettes to minors; eliminating enforcement discretion for products with youth appeal; protecting children from e-liquid dangers; requiring manufacturers to provide critical information; educating youth on the dangers of e-cigarette use; expanding "The Real Cost" campaign; and helping retailers comply with age restrictions.[24]

On January 2, 2020, FDA issued guidance finalizing its enforcement policy regarding unauthorized flavored cartridge-based e-cigarettes that appeal to children, including fruit and

[22] Perry Dinardo BA and Ellen S. Rome MD, MPH, Cleveland Clinic Journal of Medicine, *Vaping: The New Wave of Nicotine Addiction* (Dec. 2019), *available at* https://www.ccjm.org/content/86/12/789#ref-6.
[23] U.S. Food and Drug Administration, U.S. Department of Health and Human Services, *FDA's Youth Tobacco Prevention Plan, available at* https://www.fda.gov/tobacco-products/youth-and-tobacco/fdas-youth-tobacco-prevention-plan (last accessed Sept. 23, 2019).
[24] *Id.*

mint.[25] Under this policy, companies must cease manufacturing, distribution, and sale of unauthorized flavored cartridge-based e-cigarettes, other than tobacco or menthol, within 30 days or risk FDA enforcement actions. According to the policy, FDA intends to prioritize enforcement action against any flavored, cartridge-based ENDS product (other than tobacco- or menthol-flavored products); all other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and any ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors.[26]

d. Outbreak of Lung Illness Associated with Using E-cigarette Products

On August 30, 2019, the CDC released a health advisory regarding severe pulmonary disease associated with using e-cigarette products.[27] As of January 14, 2020, a total of 2,668 hospitalized e-cigarette, or vaping, product use associated lung illness (EVALI) cases or deaths have been reported to CDC from 50 states, the District of Columbia, and the U.S. territories (Puerto Rico and U.S. Virgin Islands).[28] Sixty deaths have been confirmed in 27 states and the District of Columbia—Alabama, California, Connecticut, Delaware, District of Columbia, Florida, Georgia, Illinois, Indiana, Kansas, Louisiana, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Jersey, New York, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, and Virginia.[29] The median age of the deceased patients was 51 years and ranged from 15-75 years.[30] Among the 2,668 hospitalized cases, 66 percent were male; and the median age of patients was 24 years and ranged from 13-85 years.[31] According to CDC, the data suggests that the outbreak peaked in September 2019, however states continue to report new cases.

According to CDC, Vitamin E acetate is strongly linked to the EVALI outbreak, as it has been found in product samples tested by FDA, state laboratories, and in patient lung fluid samples tested by CDC from geographically diverse states.[32] However, the evidence is not sufficient to rule out other causes. For example, "[n]ational and state data from patient reports and product sample testing suggest that [tetrahydrocannabinol] THC-containing e-cigarette, or vaping, products, particularly from informal sources like friends, family, or in-person or online

[25] U.S. Food & Drug Administration, *FDA Finalizes Enforcement Policy on Unauthorized Flavored Cartridge-Based E-Cigarettes That Appeal to Children, Including Fruit and Mint* (Jan. 2, 2020), *available at* https://www.hhs.gov/about/news/2020/01/02/fda-finalizes-enforcement-policy-unauthorized-flavored-cartridge-based-e-cigarettes.html.
[26] U.S. Food & Drug Administration, Center for Tobacco Products, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization, Guidance for Industry (Jan. 2020), *available at* https://www.fda.gov/media/133880/download.
[27] Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, *Severe Pulmonary Disease Associated with Using E-Cigarette Products* (Aug. 30, 2019), *available at* https://emergency.cdc.gov/han/han00421.asp.
[28] Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, *Outbreak of Lung Injury Associated with E-Cigarette Use, or Vaping, available at* https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#what-is-new (last accessed Jan. 23, 2020).
[29] *Id.*
[30] *Id.*
[31] *Id.*
[32] *Id.*

dealers, are linked to most EVALI cases and play a major role in the outbreak."[33] Of the 2,668 hospitalized patients, 2,022 had data on substance use. Of the 2,022 patients, 82 percent reported using THC-containing products and 33 percent reported exclusive use of THC-containing products.[34] Of the patients that reported using THC-containing products, 50 percent provided data on product source. Of those, 16 percent reported acquiring products only from commercial sources (recreational and/or medical dispensaries, vape or smoke shops, stores, and pop-up shops); 78 percent reported acquiring products from informal sources (family/friends, dealers, online, or other sources); and six percent reported acquiring products from both commercial and informal sources.[35] Of the 2,022 patients, 57 percent reported using nicotine-containing products and 14 percent reported exclusive use of nicotine-containing products.[36] Of the patients that reported using nicotine-containing products, 54 percent provided data on product source. Of those, 69 percent reported acquiring products only from commercial sources; 17 percent reported acquiring products only from informal sources; and 15 percent reported acquiring products from both commercial and informal sources.[37] These numbers are largely self-reported and thus not independently validated.

On January 17, 2020, CDC released a commentary in the New England Journal of Medicine that discusses the EVALI outbreak, the distinct differences between EVALI and the on-going youth vaping epidemic, and the implications of both for public health.[38] "The EVALI outbreak primarily effects young adults, is driven by THC-containing products from informal sources and is strongly linked to vitamin E acetate. In contrast, the youth e-cigarette, or vaping, product use epidemic primarily affects adolescents, is driven by use of nicotine-containing products obtained mostly from formal sources, and has been caused by multiple factors, including advertising, attractive flavors – particularly in cartridge-based products, and the availability of devices that are easily concealable devices that deliver high levels of nicotine."[39]

The CDC and FDA have issued recommendations for public health practice regarding e-cigarettes.[40] Included in the recommendations are that people should not use THC-containing e-cigarette, or vaping, products, particularly from informal sources; Vitamin E acetate should not be added to any e-cigarette, or vaping, products and adults using nicotine-containing e-cigarettes or vaping products as an alternative to cigarettes should not go back to smoking; youths, young adults, and women who are pregnant should never use E-cigarette, or vaping, products; the best

[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] *Id.*
[37] *Id.*
[38] Brian A. King, Ph.D., et. al., The EVALI and Youth Vaping Epidemics – Implications for Public Health, The New England Journal of Medicine (Jan. 17, 2020), *available at* https://www.nejm.org/doi/full/10.1056/NEJMp1916171.
[39] Centers for Disease Control and Prevention, Quick Facts on the Risks of E-cigarettes for Kids, Teens, and Young Adults, (accessed Jan. 29, 2020), *available at* https://www.cdc.gov/media/releases/2020/p0117-evali-cases-decline.html.
[40] Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, CDC Newsroom, Most EVALI Patients Used THC-Containing Products as New Cases Continue To Decline (Jan. 17, 2020), *available at* https://www.cdc.gov/media/releases/2020/p0117-evali-cases-decline.html.

way to avoid potentially harmful effects is to not use THC-containing e-cigarette, or vaping, products; and persons engaging in ongoing cannabis use that leads to significant impairment or distress should seek evidence-based treatment by a healthcare professional.[41]

[41] *Id.*